



UNITED STATES DEPARTMENT OF COMMERCE
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18N1/0519

REARDEN NUMBER	
ART UNIT	PAPER NUMBER
1815	10

DATE MAILED:

05/19/94

Below is a communication from the EXAMINER in charge of this application

COMMISSIONER OF PATENTS AND TRADEMARKS

ADVISORY ACTION

☒ THE PERIOD FOR RESPONSE:

- a) ☐ is extended to run _____ or continues to run 3 mos from the date of the final rejection
- b) ☐ expires three months from the date of the final rejection or as of the mailing date of this Advisory Action, whichever is later. In no event however, will the statutory period for the response expire later than six months from the date of the final rejection.

Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a), the proposed response and the appropriate fee. The date on which the response, the petition, and the fee have been filed is the date of the response and also the date for the purposes of determining the period of extension and the corresponding amount of the fee. Any extension fee pursuant to 37 CFR 1.17 will be calculated from the date of the originally set shortened statutory period for response or as set forth in b) above.

☐ Appellant's Brief is due in accordance with 37 CFR 1.192(a).

☒ Applicant's response to the final rejection, filed 5/3/94 has been considered with the following effect, but it is not deemed to place the application in condition for allowance:

1. ☒ The proposed amendments to the claim and /or specification will not be entered and the final rejection stands because:

- a. ☐ There is no convincing showing under 37 CFR 1.116(b) why the proposed amendment is necessary and was not earlier presented.
- b. ☒ They raise new issues that would require further consideration and/or search. (See Note).
- c. ☐ They raise the issue of new matter. (See Note).
- d. ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal.
- e. ☐ They present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE: See attached.

2. ☐ Newly proposed or amended claims _____ would be allowed if submitted in a separately filed amendment cancelling the non-allowable claims.

3. ☒ Upon the filing an appeal, the proposed amendment ☐ will be entered ☒ will not be entered and the status of the claims will be as follows:

Claims allowed: none

Claims objected to: _____

Claims rejected: 3, 9-10, 13-18

However;

☒ Applicant's response has overcome the following rejection(s): Rejection of claims 13-14 under 102(b)

4. ☒ The affidavit, exhibit or request for reconsideration has been considered but does not overcome the rejection because see attached

5. ☐ The affidavit or exhibit will not be considered because applicant has not shown good and sufficient reasons why it was not earlier presented.

☐ The proposed drawing correction ☐ has ☐ has not been approved by the examiner.

☐ Other

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1. The following attachment to the PTO-303 is intended to provide guidance regarding the outstanding rejection under 35 U.S.C. § 112.

5 The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 14 and 16 remain rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is fully enabling only for claims limited to the procedures demonstrated in Examples 1-3.
10 These examples show, apparently successfully, the present method applied to a variety of target substances: a sample of nucleic acid, a sample of nucleic acid with protein and a sample of phage. Each of these examples was performed on a clean, artificial mixture of the target substance and the qualitative
15 results were stated.

The remaining examples are speculative in nature as they appear to be laboratory protocols presented without even qualitative results.

20 The principle difference between the enabling examples and the non-enabling examples is in the phrases used to describe them. The enabled examples use phrases similar to "has been used" in describing the procedures. The non-enabled examples uses phrases similar to "can be used".

This phrase is speculative and is not adequate to overcome

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the reasons given below for finding the disclosure non-enabling for all the separations encompassed by the language of claims 14 and 16.

5 The present disclosure is not adequate to enable the many biopolymers, let alone non-biopolymers, encompassed by the present claim language. For instance, the isolation of nucleic acid from lysate or the isolation of blood cells from whole blood present far more challenging and impure mixtures than those demonstrated to date. These complex mixtures present physical
10 and chemical interactions where the precipitation of one species in the presence of the large surface area of the present beads may well result in the precipitation of another rather than a separation of them. See, for instance, lines 30-35 of specification page 12 where the precipitation of some species
15 agglomerate (entraps) other species. See M.P.E.P. §§ 706.03(n) and 706.03(z).

Applicant's arguments filed 5/3/94 have been fully considered but they are not deemed to be persuasive. The reasons for citing the lack of enablement is thoroughly described above.
20 Applicant appears to support this rejection by use of the term "protocol" on page 3 of the response. A protocol is insufficient to demonstrate enablement.

Applicant contends that one of skill would be able to perform the techniques of the claims. This is not well taken

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because one of skill must be able to conduct the present methods successfully without undue experimentation. In the face of the logical reasoning of non-enablement presented above, successful demonstration to overcome this burden is lacking.

5 Applicant presents sales literature in an attempt to show that one of skill would have been able to conduct the presently claimed separations. This is not persuasive because no date of publication or indication of public availability has been given for these materials. Thus examiner cannot assess if these
10 represent the level of skill at the time of filing. Additionally, applicant should compare the date of public sale or use to the filing date.

3. Claims 3, 9-10 and 13-18 remain rejected under 35 U.S.C.
15 § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

 Several terms in the claims lack proper antecedent basis in the claims. These are of record. To provide guidance for only a
20 few of the needed changes, examiner recommends insertion of the phrase --containing nucleic acid-- after "solution" into line 2 of claim 13; and insertion of the phrase --containing protein and nucleic acid-- after "solution" into line 2 of claim 15.

Examiner recommends the review of the present claims from an

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objective viewpoint to ensure a word picture of each process step is presented where all components and their sources are set forth.


5 The proposed amendment of 5/3/94 offers a number of constructive changes that would have been entered had the limitation of claim 16 to "bacteriophage" not raised a new issue. Since most bacteriophage do not have "bacterial chromosomal DNA", this phrase would have been without antecedent basis if the amendment had been entered. Further, since bacteriophage
10 typically have a single nucleic acid molecule (encompassed by the term "low weight DNA" as defined on specification page 4), the phrase "bacterial chromosomal DNA" should be deleted.

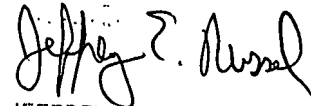
Also, instead of deleting the phrase "out of solution" from line 5 in claim 13, this phrase should be replaced with --out of
15 the solution--.

4. No claims are allowed.

20 Any inquiry concerning this communication or earlier communications from the examiner should be directed to the Group 180 receptionist whose telephone number is (703) 308-0196.

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Timothy J. Reardon
May 18, 1994


JEFFREY E. RUSSEL
PRIMARY PATENT EXAMINER
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